

### **AMENDMENTS TO THE DRAWINGS**

Applicant submits herewith replacement drawing sheets for FIGS. 9, 10, 13, 14, 16, 23, and 24. No new matter has been added by way of this amendment.

Applicants' specification refers to "connector 107" in the description of both FIG. 9 and FIG. 10. However, reference number "107" was inadvertently omitted from FIGS. 9 and 10. The attached sheets include new versions of FIGS. 9 and 10 incorporating the omitted reference number "107." In addition, Applicants' specification refers to "button moldings 100, 102" in the description of FIG. 10. However, reference numbers "100" and "102" were inadvertently omitted from FIG. 10. The new version of FIG. 10 included in the attached sheets also incorporates the omitted reference numbers "100" and "102."

Applicants' specification refers to "connector 113" in the description of both FIG. 13 and FIG. 14. However, reference number "113" was inadvertently omitted from FIGS. 13 and 14. The attached sheets include new versions of FIGS. 13 and 14 incorporating the omitted reference number "113." In addition, Applicants' specification refers to "display circuit board 104" and "antenna circuit board 106" in the description of FIG. 14. However, the display circuit board illustrated by FIG. 14 was inadvertently improperly identified with reference number "106" and the antenna circuit board illustrated by FIG. 14 was inadvertently improperly identified with reference number "104." The new version of FIG. 14 included in the attached sheets replaces the incorrect reference number "104" with the correct reference number "106" for the antenna circuit board, and replaces the incorrect reference number "106" with the correct reference number "104" for the display circuit board.

Applicants' specification refers to "antenna circuit board 106" in the description of FIG. 16. However, the antenna circuit board illustrated by FIG. 16 was inadvertently improperly identified with reference number "104." The attached sheets include a new version of FIG. 16 that replaces the incorrect reference number "104" with the correct reference number "106" for the antenna circuit board. In addition, Applicants' amended specification refers to "antenna circuit board 106" in the description of FIGS. 23 and 24. However, the antenna circuit board illustrated by FIGS. 23 and 24 was inadvertently improperly identified with reference number "104." The attached sheets include new versions of FIGS. 23 and 24 that replace the incorrect reference number "104" with the correct reference number "106" for the antenna circuit board.

The attached sheets include a new version of FIG. 9 incorporating the omitted reference number "107," a new version of FIG. 10 incorporating the omitted reference numbers "100", "102", and "107," a new version of FIG. 13 incorporating the omitted reference number "113," a new version of FIG. 14 incorporating the omitted reference number "113" and correcting the reference numbers for display circuit board "104" and antenna circuit board "106," and new versions of FIGS. 16, 23, and 24 correcting the reference number for antenna circuit board "106."

Attachment: Replacement Sheets (7)

## **REMARKS**

This Amendment is responsive to the Office Action dated June 1, 2006. Applicant has amended claims 1, 2, 12, 14, 16, and 17. In addition, Applicant has added new claim 32. Claims 22-31 were withdrawn from consideration, and have now been canceled. Accordingly, claims 1-12, 14-21, and 32 are pending.

### **Objections to Drawings and Specification**

In the Office Action, the Examiner noted various reference number issues and typographical issues. Applicant has amended the drawings and the specification to address the issues identified by the Examiner.

### **Claim Objections**

The Examiner objected to claim 14 on the basis of indefiniteness of the limitation “opposite the second circuit board.” The Examiner suggested that Applicant amend the claim to add “language that imparts definite function, such as – positioned on the first circuit board to avoid noise and electromagnetic interference from the second board.”

Applicant believes that the functional definition suggested by the Examiner is not necessary as claim 14 is neither vague nor indefinite. Nevertheless, Applicant has amended claim 14 to more clearly specify that the internal antenna is mounted to the first circuit board on a side of the first circuit board facing away from the second circuit board to reduce electromagnetic interference. Applicants respectfully submit that claim 14 is sufficiently definite.

### **Claim Rejection Under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1-7, 10, 17, 20 and 21 under 35 U.S.C. 102(b) as being anticipated by Causey, III et al. (US 2002/0002326). The Examiner also rejected claims 1-10, 17 and 19-21 under 35 U.S.C. 102(b) as being anticipated by Meadows et al. (US 6,516,227).

Applicant respectfully traverses the rejections under section 102, to the extent they may be considered applicable to claims 1-7, 10, 17, 20 and 21, as amended. Causey and Meadows fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b),

and provide no teaching that would have suggested the desirability of modification to include such features.

**Causey**

Causey fails to disclose or suggest a medical device programmer comprising a medical device programmer comprising an infrared interface to receive changes to software executed by a processor within the programmer during an infrared communication session, and a controller to activate the infrared interface to seek an infrared communication session for a finite period of time in response to power-up of the programmer, and deactivate the infrared interface after the finite period of time if the infrared communication session is not established, as recited by Applicant's amended claim 1.

In support of the rejection, the Examiner characterized Causey as disclosing an infrared interface to receive changes to software executed by a processor within the medical device programmer, citing paragraphs [0068], [0080], [0086] and [0098]. The Examiner seemed to acknowledge that Causey does not disclose or suggest initiating an infrared communication session in response to power-up of the programmer, nor for a finite period of time. However, the Examiner asserted that such features are inherent in the Causey system.

Applicant disagrees with the Examiner's conclusion of anticipation, particularly to the extent it may be considered applicable to amended claim 1, which clarifies some of the features of the claimed medical device programmer. Activation of an infrared interface in response to power up, and seeking an infrared communication session for a finite period of time upon activation are neither disclosed nor suggested in Causey, nor inherent in the teachings of Causey.

Causey does not disclose or suggest activation of an infrared interface in response to power-up of a medical device programmer. In his analysis, the Examiner stated that initiation of an infrared communication session in response to power-up is inherent because "the IR link has to be initiated and active for any data to be transceived between the patient programmer and it's programming device." Although the infrared interface must be initiated and active for data to be transceived, it is not necessary for the activation of the infrared interface to occur in response to power-up of the programmer, as required by Applicant's claims.

The Causey reference makes no mention of when an infrared communication session is initiated, or any control mechanism for activating an infrared interface. Causey clearly fails to disclose or suggest activation of an infrared interface in response to power-up. To support inherency, the Examiner must provide a basis in fact or technical reasoning to support that the allegedly inherent characteristic necessarily flows from the teachings of Causey.<sup>1</sup> The Examiner has not explained why activation of an infrared interface in response to power-up would necessarily flow from the teaching of an infrared interface in Causey. Absent such a showing, Causey cannot anticipate claim 1.

Causey also does not disclose or suggest activation of an infrared interface in response to power-up to seek an infrared communication session for a finite period of time. In his analysis, the Examiner reasoned that, because a computer program is of finite length, an infrared communication session used to transfer such a program also must be inherently finite in length. This rationale is inapplicable to the actual language of Applicant's claims. As recited in claim 1, the finite period of time does not apply to the communication session, but rather the seeking of a communication session upon activation of the infrared interface in response to power-up.

Consistent with Applicant's disclosure, the claims require that seeking an infrared communication session is limited by a finite period of time. For example, Applicant's disclosure, at paragraph [0026], states that "the infrared interface enters a programming state, i.e., a limited listening period, in which it is capable of establishing an infrared communication session for field updates and upgrades to the embedded operating system." Causey provides no such teaching. Even if a software update of finite length is transferred, the finite length limitation in claim 1 pertains not to the session but the limited listening period during which the infrared interface seeks a session.

The Examiner additionally stated that, even if an infrared port was constantly in communication when the device is turned on, the powering down of the device would constitute a finite end to the infrared communication session. Again, the finite period of time in claim 1 refers not to the communication session, but to the time during which the infrared interface seeks a communication session following power-up of the medical device programmer. Moreover, in the scenario described by the Examiner, termination of either an infrared communication session

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<sup>1</sup> *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

or the seeking of a communication session by powering down the device would not take place under control by a controller, as set forth in claim 1.

The Causey reference simply makes no mention of a controller to activate the infrared interface to seek an infrared communication session for a finite period of time in response to power-up of the programmer, as recited by Applicant's amended claim 1. In view of the differences identified above, Causey does not support a prima facie case of anticipation with respect to claim 1. Therefore, the rejection of claims 1-7, 10, 17, 20 and 21 should be withdrawn.

Causey also fails to disclose or suggest various features set forth in the dependent claims, some of which are discussed below. As one example, with respect to claims 2 and 20, Causey does not describe a particular time during which the infrared interface is active to seek a communication session. With respect to claim 2, Causey fails to disclose an infrared interface that is active for approximately 5 to 10 seconds following power-up to seek a communication session. Similarly, Causey does not specify a finite period of time for seeking a communication session that is less than or equal to approximately 10 seconds following power-up.

The Examiner reasoned that, even if a system remains in use for an hour, it is still active for at least 5 to 10 seconds. Applicant disagrees with this reasoning. However, amended claim 1 now specifies that the controller deactivates the infrared interface after the finite period of time if the infrared communication session is not established. Therefore, this reasoning does not apply to claims 2 and 20.

In view of the fundamental differences identified above, Applicant reserves comment concerning the further differences expressed in the various dependent claims. However, Applicant neither admits nor acquiesces in the propriety of the Examiner's analysis with respect to such claims.

### **Meadows**

Like Causey, Meadows also fails to disclose or suggest a medical device programmer comprising a medical device programmer comprising an infrared interface to receive changes to software executed by a processor within the programmer during an infrared communication session, and a controller to activate the infrared interface to seek an infrared communication

session for a finite period of time in response to power-up of the programmer, and deactivate the infrared interface after the finite period of time if the infrared communication session is not established, as recited by Applicant's amended claim 1.

In support of the rejection, the Examiner stated that Meadows teaches the establishment of an infrared link for a finite period of time "each time the patient or medical personnel change a stimulus parameter or initiate a charging session . . . , which means that each communication must necessarily terminate at some time before the next begins." The Examiner also stated that it is inherent that the Meadows handheld programmer initiates an infrared communication session in response to power-up so that the handheld programmer is always appropriately synchronized with a clinician programmer.

Applicant disagrees with the Examiner's conclusion of anticipation, particularly to the extent it may be considered applicable to amended claim 1. As mentioned above with respect to Causey, the finite period of time set forth in claim 1 does not refer to the communication session, but rather the seeking of a communication session upon activation of the infrared interface in response to power-up. Even if multiple communication sessions are established in the Meadows system, the duration of each session is not the pertinent issue. Again, the finite length limitation in claim 1 pertains not to the session but the limited listening period during which the infrared interface seeks a session.

In addition, the rationales stated with respect to the finite period of time and the power-up limitations appear to be inconsistent. For example, the Examiner stated that a telecommunication link is established each time the patient or medical personnel make a change or initiate a charging session. Yet, with respect to the power-up limitation, the Examiner seemed to suggest that the programmers in Meadows would initiate a communication session upon power-up to ensure that the programmers are "always appropriately synchronized." On the one hand, the Examiner acknowledged that Meadows teaches synchronization when a change occurs. On the other hand, the Examiner speculated that Meadows would also initiate a communication session upon power-up, apparently whether a change has occurred or not.

Meadows does not state that the programmers are constantly or always in communication, and certainly does not describe activation of an infrared interface upon power-up. Instead, Meadows states that the programmers are appropriately synchronized so that changes in one

programmer or reflected in the other programmer. It does not inherently follow that the programmers in Meadows initiate an infrared communication session upon power-up. Nor does Meadows provide any pertinent teaching in this regard. Rather, it is just as plausible that Meadows initiates an infrared communication session in response to a change in a stimulus parameter. Again, to support inherency, the Examiner must provide a basis in fact or technical reasoning to support that the allegedly inherent characteristic necessarily flows from the teachings of Meadows.<sup>2</sup> Absent such a showing, Meadows cannot anticipate claim 1.

The Meadows reference simply makes no mention of a controller to activate the infrared interface to seek an infrared communication session for a finite period of time in response to power-up of the programmer, as recited by Applicant's amended claim 1. In view of the differences identified above, Meadows does not support a prima facie case of anticipation with respect to claim 1. Therefore, the rejection of claims 1-7, 10, 17, and 19-21 should be withdrawn.

Meadows also fails to disclose or suggest various features set forth in the dependent claims, some of which are discussed below. As one example, with respect to claims 2 and 20, Meadows does not describe a particular time during which the infrared interface is active to seek a communication session. With respect to claim 2, Meadows fails to disclose an infrared interface that is active for approximately 5 to 10 seconds following power-up to seek a communication session. Similarly, Meadows does not specify a finite period of time for seeking a communication session that is less than or equal to approximately 10 seconds following power-up, as set forth in claim 20.

The Examiner reasoned that, even if the Meadows system remains in use for an hour, it is still active for at least 5 to 10 seconds. Applicant disagrees with this reasoning. However, amended claim 1 now specifies that the controller deactivates the infrared interface after the finite period of time if the infrared communication session is not established. Therefore, this reasoning does not apply to claims 2 and 20. The Examiner further speculated that the infrared interface could be deactivated if a patient or clinician powers down the programmer after 8 seconds. Yet, even if such a rationale were sound, there is no controller in the Meadows programmer that would deactivate the infrared interface after the stated time period. In other

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<sup>2</sup> *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)



words, even if the the seeking of a communication session were ended by powering down the Meadows device, there is no finite period of time that is determined by a controller that controls the infrared interface, as further required by Applicant's claims.

In view of the fundamental differences identified above, Applicant reserves comment concerning the further differences expressed in the various dependent claims. However, Applicant neither admits nor acquiesces in the propriety of the Examiner's analysis with respect to such claims.

In summary, Meadows fails to disclose each and every limitation set forth in claim 1. Claims 2-7, 10, 17, and 19-21 are dependent on claim 1, and are also in condition for allowance. Meadows fails to disclose each and every limitation set forth in claim 1. Claims 2-10, 17, and 19-21 are dependent on claim 1, and are also in condition for allowance. For at least these reasons, the applied references have failed to establish a prima facie case for anticipation of Applicant's claims 1-10, 17, and 19-21 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

#### **Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 11, 12, 14, 15 and 18 under 35 U.S.C. 103(a) as being unpatentable over Meadows et al and rejected claim 16 under 35 U.S.C. 103(a) as being anticipated by Meadows et al. in view of Stanton et al. (US 6,249,703). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

#### ***Claims 11, 12, and 14***

Applicant traverses the rejection of claims 11, 12, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Meadows. Claims 11, 12, and 14 are dependent upon claim 1. Meadows fails to disclose or suggest the requirements of claim 11, 12 and 14 for at least the reasons stated previously in this Amendment with respect to claim 1. Therefore, claims 11, 12, and 14 are also in condition for allowance. Withdrawal of this rejection is requested.

Additionally, Applicant disagrees with the Examiner's analysis of Meadows. In support of the rejection, the Examiner stated that it would have been an obvious matter of design choice to modify the Meadows system with two circuit boards to simplify manufacturing or reduce the size of the device.

Unsupported conjecture about design choice is not a proper basis for rejection of claim 11. It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.<sup>3</sup> In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.<sup>4</sup> A prima facie case of obviousness is established only when this burden is met. A finding of obviousness must be based upon substantial evidence, and not baseless conjecture.<sup>5</sup>

Deficiencies in the evidentiary record cannot be cured by general conclusions such as "general knowledge" or "common sense."<sup>6</sup> Accordingly, the rejection cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.<sup>7</sup> Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to incorporate the features of Applicant's dependent claims, claim 11 should be allowed.

Applicant's claim 11 describes a first circuit board within the programmer housing, the first circuit board including telemetry circuitry, wherein the telemetry circuit is coupled to an antenna and a second circuit board within the programmer housing, the second circuit board including a display and display circuitry. As disclosed by the Applicant, the separation distance between the circuit boards may serve to reduce the effects of electrical and electromagnetic interference caused by the display on signals transmitted and received by the internal antenna.

In addition, the placement of the antenna and display electronics on different circuit boards may reduce electrical and electromagnetic interference. Paragraph [0120]. One of ordinary skill in the art would have appreciated the advantages of such a feature only upon access

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<sup>3</sup> *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

<sup>4</sup> *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

to Applicant's disclosure, which is impermissible. Claims 12 and 14 are dependent on claim 11 and are also in condition for allowance.

***Claim 15***

Applicant traverses the rejection of claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Meadows. Claim 15 is dependent upon claim 1. Meadows fails to disclose or suggest the requirements of claim 15 for at least the reasons stated previously in this Amendment with respect to claim 1. Therefore, claim 15 is also in condition for allowance. Withdrawal of this rejection is requested.

Additionally, the Examiner stated that modification of the Meadows device would have been obvious as a matter of design choice. Again, Applicant disputes the Examiner's reliance on mere design choice. Rather, the Examiner must identify a teaching in the prior art that would have suggested the requisite modification.

The Examiner also stated that Applicant has not disclosed that positioning the batteries inside the aperture defined by the internal antenna provides an advantage, is used for a particular purpose, or solves a stated problem. Even if it were pertinent to the issue of obviousness, which Applicants dispute, the Examiner's statement is plainly incorrect. Applicant's disclosure states positioning of a battery bay to extend at least partially into an aperture defined by the internal antenna can reduce external magnetic interference to the internal antenna by providing an RF load to the internal antenna, enhancing noise immunity. Paragraph [0100].

The Examiner did not identify any prior art teaching that would have suggested the features recited in claim 15. Moreover, one of ordinary skill in the art would have appreciated the advantages of such a feature only upon access to Applicant's disclosure, which is impermissible.

***Claim 16***

Applicant traverses the rejection of claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Meadows in view of Stanton et al. Claim 16 is dependent upon claim 1. Meadows fails to disclose or suggest the requirements of claim 1 for at least the reasons stated previously in this Amendment. Stanton lacks any teaching sufficient to overcome the basic

deficiencies described above with respect to Meadows. Therefore, claim 16 is also in condition for allowance. Withdrawal of this rejection is requested.

***Claim 18***

Applicant traverses the rejection of claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Meadows. Claim 18 is dependent upon claim 1. Meadows fails to disclose or suggest the requirements of claim 1 for at least the reasons stated previously in this Amendment. Therefore, claim 18 is also in condition for allowance. Withdrawal of this rejection is requested.

**CONCLUSION**

In light of the fundamental deficiencies in the primary references, e.g., Causey and Meadows, Applicant has generally withheld comment on the other applied references. Applicant has done so for purposes of brevity and conciseness and neither admits nor acquiesces in the legitimacy of the prior art references relative to the claimed invention.

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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